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**PDUFA**  
**FDA and Stakeholders Public Meeting**  
**September 15, 2000**  
**Agenda**

**9:00 am**                      **Welcome**                      Mark Barnett, Moderator

**9:10 am**                      **Opening Remarks**                      Jane Henney, M.D.

**9:20 am –**  
**10:00 am**                      **Panel I - Presentations by FDA**

- Linda Suydam, D.P.A.  
Senior Associate Commissioner, FDA
- Janet Woodcock, M.D.  
Director, Center for Drug Evaluation and Research, FDA
- Kathy Zoon, Ph.D.  
Director, Center for Biologics Evaluation and Research, FDA

**10:00 am –**  
**11:00 am**                      **Panel II - Presentations by Patient Advocacy Groups**

- Abbey Meyers  
President, The National Organization for Rare Disorders
- Jeff Bloom  
Patient Representative
- Carl Dixon  
Executive Director, Kidney Cancer Association
- Myrl Weinberg, CAE  
President, National Health Council

**11:00 am –**  
**11:15 am**                      **Break**

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**11:15 am –  
12:15 pm**

**Panel III - Presentations by Consumer Protection Groups**

- Cindy Pearson  
Executive Director, National Women's Health Network
- Larry Sasich, Pharm.D., M.P.H., FASHP  
Pharmacist, Public Citizen
- Brett Kay  
Program Associate, National Consumer League
- Arthur Levin, M.P.H.  
Director, Center for Medical Consumers

**12:15 pm –  
1:30 pm**

**Lunch**

**1:30 pm –  
2:30 pm**

**Panel IV - Presentations by Industry Groups**

- Larry Versteegh, Ph.D.  
Vice President, Procter and Gamble Pharmaceuticals
- Carl Feldbaum  
President, Biotechnology Industry Organization
- Christopher Pelloni  
Vice President of Research and Development, TEVA  
Pharmaceuticals USA
- Robert Milanese  
President, National Association of Pharmaceutical  
Manufacturers

**2:30 pm –  
2:40 pm**

**Break**

**2:40 pm –  
3:40 pm**

**Panel V - Presentations by Health Professional Groups and  
Academic Research**

- Joe Cranston, Ph.D.  
Director of Science, Research and Technology, American  
Medical Association

- John Gans, Pharm.D.  
Executive Vice President, American Pharmaceutical  
Association
- Richard Levinson. M.D., D.P.A.  
Associate Executive Director, American Public Health  
Association
- Kenneth Kaitin, Ph.D.  
Director, Tufts Center for the Study of Drug Development
- Stuart Walker  
Director, Centre for Medicines Research International

3:40 pm

**Open Public Comment Period**